

JAN. 4. 2005 5:12PM

PABST PATENT GROUP

NO. 2641 P. 1

RECEIVED
CENTRAL FAX CENTER

JAN 04 2005

PABST PATENT GROUP



Pabst Patent Group LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, GA 30361

Telephone (404) 879-2150
Telefax (404) 879-2160

information@pabstpatent.com
www.pabstpatent.com

TELEFAX

Date: January 4, 2005 **Total pages:** 13 including cover

To: Examiner Edward J. Webman **Telephone:** 571-272-0633 **Telefax:** 703-872-9306

From: Rivka Monheit **Telephone:** 404-879-2152 **Telefax:** (404) 879-2160

Our Docket No. ACU 109 CIP
Your Docket No. **Client/Matter No.** 077586/00027

Please call (404) 879-2150 if you did not receive all of the pages, or if they are illegible.

CONFIDENTIALITY NOTICE: This facsimile, along with any documents, files, or attachments, may contain information that is confidential, privileged, or otherwise exempt from disclosure. If you are not the intended recipient or a person responsible for delivering it to the intended recipient, you are hereby notified that any disclosure, copying, printing, distribution or use of any information contained in or attached to this facsimile is strictly prohibited. If you have received this facsimile in error, please immediately notify us by facsimile or by telephone collect at the numbers stated above, and destroy the original facsimile and its attachments without reading, printing, or saving in any manner. Your cooperation is appreciated. Thank you.

MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering III, Sarwat Khattak, and Greg Randall

Serial No.: 10/053,929 **Art Unit:** 1617

Filed: January 22, 2002 **Examiner:** Edward J. Webman

For: *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

AMENDMENT AND RESPONSE AND TERMINAL DISCLAIMER

45053394.1

ACU 109 CIP
077586/00027

PTO/SB/21 (09-04)

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(To be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/053,929
Filing Date	January 22, 2002
First Named Inventor	Straub et al.
Art Unit	1617
Examiner Name	Edward J. Webman
Total Number of Pages in This Submission	12
Attorney Docket Number	ACU 109 CIP

ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input checked="" type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Two Statements Under 37 CFR 3.73(b)
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	<input type="checkbox"/> Remarks
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Pabst Patent Group LLP		
Signature	<i>Rivka D. Monheit</i>		
Printed name	Rivka D. Monheit		
Date	January 4, 2005	Reg. No.	48,731

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	<i>Carla Stone</i>
Typed or printed name	Carla Stone
Date	January 4, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/17 (12-04)

Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2005

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 65.00)

<i>Complete if Known</i>	
Application Number	10/053,929
Filing Date	January 22, 2002
First Named Inventor	Straub et al.
Examiner Name	Edward J. Webman
Art Unit	1617
Attorney Docket No.	ACU 109 CIP

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Charge fee(s) indicated below | <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee |
| <input checked="" type="checkbox"/> Charge any additional fee(s) or underpayments of fee(s)
under 37 CFR 1.16 and 1.17 | <input checked="" type="checkbox"/> Credit any overpayments |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		<u>Fees Paid (\$)</u>
	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

2. EXCESS CLAIM FEES

Fee Description Small Entity
Fee (\$) Fee (\$)

Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent

50

25

Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent

200

100

Multiple dependent claims

360

180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims
6 - 33 or HP =	0	x	=	<u>Fee (\$)</u> <u>Fee Paid (\$)</u>

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	<u>Fee (\$)</u> <u>Fee Paid (\$)</u>
1 - 3 or HP =	0	x	=	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x	=	_____

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: Terminal Disclaimer \$65.00

SUBMITTED BY

Signature	<u>Rivka D. Monheit</u>	Registration No. (Attorney/Agent)	48,731	Telephone	(404) 879-2152
Name (Print/Type)	Rivka D. Monheit	Date	January 4, 2005		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ACU 109 CIP 077586/00027

JAN. 4. 2005 5:13PM

PABST PATENT GROUP

NO. 2641 P. 4

RECEIVED
CENTRAL FAX CENTER
JAN 04 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering III,
Sarwat Khattak, and Greg Randall

Serial No.: 10/053,929 Art Unit: 1617

Filed: January 22, 2002 Examiner: Edward J. Webman

For: *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE

Sir:

Responsive to the Office Action mailed on October 7, 2004, please amend the application as follows. Submitted with this Amendment and Response is a Terminal Disclaimer and two Statements Under 37 C.F.R. §3.73(b). The Commissioner is hereby authorized to charge \$65.00, the Terminal Disclaimer fee for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

45053080v1

1

ACU 109 CIP
077586/00027

U.S.S.N. 10/053,929

Filed: January 22, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

Claims 1-15. (Canceled)

16. (Currently amended) A method for making a pharmaceutical composition comprising ~~comprising~~ a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5 μm and a total surface area greater than about 0.5 m^2/mL , and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0 g/mL and having a total surface area of greater than or equal to 0.2 m^2/g , comprising

- (a) dissolving a drug in a volatile solvent to form a drug solution,
- (b) combining at least one volatile solid pore forming agent with the drug solution to form an emulsion, suspension, or second solution,
- (c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and
- (d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient.

17. (Original) The method of claim 16 wherein step (d) is conducted using a process selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof.

U.S.S.N. 10/053,929

Filed: January 22, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION

18. (Original) The method of claim 16 wherein the excipients are selected from the group consisting of polymers, amino acids, wetting agents, sugars, preservatives, pegylated excipients, tonicity agents, and combinations thereof.

19. (Original) The method of claim 16 wherein the matrix comprises between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

20. (Original) The method of claim 16 wherein the pore forming agent is a volatile salt.

21. (Original) The method of claim 20 wherein the volatile salt is selected from the group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof.

Claims 22-33. (Canceled)